MAR 1 1 2014

Traditional 510(k) Summary
as required by 21 CFR 807.92(a)
K133483

A) Submitted by:	Portable Therapeutix 4254 Bluebonnet Dr Stafford, TX 77477 1-617-331-7524
Contact:	Sharyn Orton, Ph.D. MEDIcept, Inc. 200 Homer Ave Ashland, MA 01721 401-330-8264
Date prepared:	January 31, 2014
B) Classification Name:	Massager, Powered Inflatable Tube – Product code IRP Pack, Cold, Reusable – Product code IME
Common Name:	Powered inflatable tube massager Cold Pack
Proprietary Name:	Portable Therapeutix Squid Active Cold Compression device and Cold Pack for OTC Use
Device Regulations: and Class	21 CFR 890.5650, Class II 21 CFR 890.5700, Class I 510(k) exempt
Product Codes:	IRP; IME
C) Predicates:	K123829 Portable Therapeutix Squid Active Cold Compression Cold Pack

D) Device Description:

The Squid Active Cold Compression device and Cold Pack for OTC Use combines intermittent compression with cold therapy. The Squid simulates kneading and stroking of tissues using an inflatable garment attached to a gel ice pack and connected to a pre-programmed air pump. The Squid may be used for the leg, foot, feet, arm, shoulders, lower back, and hands.

The device is manufactured with the following components:

1. A portable external pump-controller unit containing the pneumatic compressor (air pump) that may be run on AC-DC external power supply or a built-in lithium battery.
2. A wrap that contains an air bladder with sequential compression capability and Velcro attachments for the cold pack. The wrap connects to the pump controller via a flexible tube. There may also be an accessory piece to the wrap to provide an additional securing mechanism. Wraps come in two configurations and three sizes.
3. Reusable thermogel cold pack

The Squid Active Cold Compression device and Cold Pack was cleared for marketing as a prescription use device in K123829. The Squid Active Cold Compression device and Cold Pack described in this 510(k) Summary will be marketed as an over-the-counter (OTC) use device.

E) Intended Use/Indication for Use:

> The Squid Active Cold Compression device and Cold Pack for OTC use is indicated for the temporary relief of minor muscle aches and pains.
>
> The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment.
>
> The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.

F) Comparison to Predicate Device(s):

The Portable Therapeutix Squid Active Cold Compression device and Cold Pack for OTC use is the same device as K123829. There were no changes to the K123829 device.

	Portable Therapeutix Squid Active Cold Compression device and Cold Pack for OTC Use	**Portable Therapeutix Squid Active Cold Compression device and Cold Pack K123829**
Product code	IRP; IME	IRP; IME
Indication for Use	The Squid Active Cold Compression device and Cold Packfor OTC use is indicated for the temporary relief of minor muscle aches and pains. The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment. The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.	The Squid Active Cold Compression device and Cold Pack is indicated for the temporary relief of minor muscle aches and pains. The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment. The cold pack is indicated for localized therapy in situations where a physician determines that cold temperature therapy is necessary or desirable.
Target	Leg, foot, arm, shoulders, lower back, hands	
OTC use	Yes	No

	Portable Therapeutix Squid Active Cold Compression device and Cold Pack	Portable Therapeutix Squid Active Cold Compression device and Cold Pack K123829
Principle of Operation/ Mechanical characteristics	Intermittent compression 4 intensity settings (modes) 1 – 30 mm Hg 2 – 50 mm Hg 3 – 70 mm Hg 4 – 85 mm Hg	
Pressure range	0 – 85 mm Hg	
Total treatment time	15 minutes	
Pressure control	Microprocessor and pressure sensor	
Inflation by	Pressurization pump	
Deflation by	Exhaust valve	
Power source	120V 60 Hz, consumption 26W; AC adapter: 120V 60 Hz, consumption 36W Lithium battery	
Cold Pack	Yes	

Substantial Equivalence Discussion

The Portable Therapeutix Squid Cold Compression System for OTC use is the same device as the FDA cleared Squid. Treatment targets, total treatment time and mechanical intermittent compression are the same. There is no change to the software, materials used, or power source. There is the addition of alignment markers on the wraps and gel pack to assist in the aligning the wrap with the gel pack for Velcro attachment.

The Portable Therapeutix Squid Cold Compression System has the same indications for use as the predicate device, with the addition of OTC use.

Performance Testing

There were no changes to the K123829 device. The following were described or testing successfully performed and reported in FDA cleared K123829:

- Biocompatibility
- Electrical Safety/EMC (including batteries)
- Bench testing including the following tests: Baseline Verification;Compression Bladder Leak Verification Test; Blow out Valve Test; Gel Pack Seal Leak Test; Low Pressure Verification Test; Max Pressure, -Total Time, -Max Compression Time, -

Min Compression Time, -Max Deflation Time, -Min Deflation Time, -Pressure Gauge Data; Solenoid Valve Release Test (High pressure release)

- Shelf life of batteries and gel pack
- Reprocessing/sterilization - the device is reusable and not supplied sterile. Cleaning instructions are included in the Instructions for Use.

For this application (K133483) a summative Usability Study was successfully conducted on representative users for OTC use. Findings from the study served to validate that the Squid - Active Cold Compression device and Cold Pack is usable by the devices' intended users.

Conformity to Standards

There is no change in conformance standards from K123829. The Squid complies with:

- IEC 60601-1:1988 + A1:1991 + A2:1995 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995).
- IEC 60601-1-2:2007 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and Tests

Conclusion

The Portable Therapeutix Squid Cold Compression System device and Cold Pack for OTC use is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 11, 2014

Portable Therapeutix, LLC
c/o MEDIcept, Inc.
Attn: Sharyn Orton Ph.D., Senior Consultant
200 Homer Avenue
Ashland, MA 01721

Re: K133483
Trade Name: Portable Therapeutix Squid Active Cold Compression Device and Cold Pack for OTC use
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP, IME
Dated: February 5, 2014
Received: February 7, 2014

Dear Dr. Orton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133483

Device Name
Portable Therapeutix Squid Active Cold Compression device and Cold Pack for OTC use

Indications for Use *(Describe)*
The Squid Active Cold Compression device and Cold Pack for OTC use is indicated for the temporary relief of minor muscle aches and pains.

The compression device is indicated for temporary increase in circulation of the treated areas in people who are in good health, and simulates kneeding and stroking of tissues using an inflatable garment.

The cold pack is indicated for localized therapy in situations where cold temperature therapy is necessary or desirable.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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